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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,978	10/31/2001	Mark D. Markel	A-70829/ENB/VEJ	4719
23715	7590	06/01/2004		
JOEL R. PETROW			EXAMINER	
SMITH & NEPHEW, INC.			ROANE, AARON F	
1450 BROOKS ROAD				
MEMPHIS, TN 38116			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,978	MARKEL, MARK D.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 12-17,25 and 26 is/are allowed.
- 6) Claim(s) 1-11,18,19,21 and 22 is/are rejected.
- 7) Claim(s) 20,23 and 24 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/02,3/14/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>IDS 9/10/2003</u> . |

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DETAILED ACTION

Withdrawal of Finality

Due to the incorrect application of the prior art of record concerning the rejections of claims 12-17 and 24-26 of the previous office actions, the finality of the office action is withdrawn.

Double Patenting

Applicant is advised that should claim 20 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 18, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (USPN 6,066,134) in view of Curley et al. (USPN 6,328,735 B1) and in further view of Underwood et al. (USPN 6,264,651 B1).

Regarding claims 1-3, 5-10 and 19, Eggers et al. disclose an electrosurgical device and method of use comprising providing a probe (10) having a proximal end and an electrode at a distal end (58); providing an irrigation solution (21), delivering the irrigating solution into an arthroscopic environment to substantially fill the arthroscopic environment with

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irrigating solution, introducing the distal extremity of the probe into the arthroscopic environment, positioning the electrode adjacent the surface of the tissue, supplying thermal energy to the electrode so as to treat the tissue whereby the irrigating solution inhibits undesirable heating below the surface of the tissue, and aspirating the irrigating solution through a lumen in the probe, see abstract, col. 2, lines 15-20, col. 3, lines 4-16, 64-67, col. 4, lines 15-50 and col. 5, lines 18-40 and figures 1-25. Eggers et al. further disclose a saline solution, see col. 2, lines 14-20, col. 3, lines 4-16 and col. 7, lines 57-59. Eggers et al. further disclose supplying radio frequency to the active electrode (58) and the return electrode (56) carried on the distal end of the probe through a radio frequency generator (28), see col. 4, lines 14-36 and col. 13, lines 19-36 and figures 1-11. Eggers et al. further disclose monitoring the temperature within the arthroscopic environment with a temperature measuring device and adjusting the amount of energy supplied to the electrodes in response to the temperature, see col. 14, lines 1-18, lines 46-62 and claim 25. Finally, Eggers et al. disclose an embodiment wherein an aspiration lumen (262) is provided, see col. 17, lines 41-54, col. 19, lines 28-41 and figure 9. Eggers et al. fail to disclose that a warm solution is used for irrigation and that the lumen has a distal opening located within a cavity defined by the probe and that the electrode is disposed in the cavity. Eggers et al. also fail to explicitly recite that the temperature sensor is carried by the distal extremity of the probe. Curley et al. disclose a thermal ablation system and method and teach the use of supplying a warmed or heated (heated above body temperature, preferably to 50° C, see col. 5, lines 29-35) saline solution in order reduce

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charring and impedance rises normally occurring in treated tissue and convect the thermal energy deeper into the tissue, see col. 3 lines 14-45. Underwood et al. disclose a device and method very similar to that of Eggers et al. and teach an alternate arthroscopic method of treatment by placing the electrode (160) in a cavity (most right portion of opening within 162) wherein the opening is the distal end opening of an aspiration lumen (162), see col. 21, line 42 through col. 22, line 18 and figure 10. It is well known in the art to place a temperature sensor at the distal extremity of the probe, adjacent to the energy emitting electrodes in order to sense the temperature. As an example, Underwood et al. teach the inclusion of "a temperature controller coupled to one or more temperature sensors at or near the distal end of the probe. The controller adjusts the output voltage of the power supply in response to a temperature set point and the measured temperature value," see col. 6, lines 23-36. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Eggers et al., as taught by Curley et al., to supple a warmed or heated saline solution in order reduce charring and impedance rises normally occurring in treated tissue and convect the thermal energy deeper into the tissue, and as further taught by Underwood et al., to provide an alternate yet equivalent arthroscopic treatment by placing the electrode in a cavity wherein the opening is the distal end opening of an aspiration lumen, and finally as is well known in the art and shown by Underwood et al., to "include a temperature controller coupled to one or more temperature sensors at or near the distal end of the

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probe. The controller adjusts the output voltage of the power supply in response to a temperature set point and the measured temperature value.”

Regarding claim 4, Eggers et al. in view of Curley et al. and in further view of Underwood et al. disclose the claimed invention. Eggers et al. in view of Curley et al. and in further view of Underwood et al. is silent as to the tissue bath. However Applicant asserts the well known equivalence between the tissue bath heating means and “other means known in the art”, see page 7, lines 23-25.

Regarding claim 11, Eggers et al. disclose the claimed invention, see claims 2-7.

Regarding claim 18, Eggers et al. discloses the claimed invention wherein “delivering the solution comprises pressurizing the arthroscopic environment.” Inherently the introduction of a foreign or outside fluid into a body cavity involves pressurizing the arthroscopic environment.

Regarding claim 21, Eggers et al. disclose the claimed invention, see col. 19, lines 15-28 and figure 7.

Regarding claim 22, Eggers et al. disclose the claimed invention, see col. 9, line 50 through col. 10, line 4, col. 12, lines 44-62.

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Allowable Subject Matter

Claims 12-17, 25 and 26 are allowed.

Claims 20 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments, see beginning on page 2 of 3, line 14, filed 4/08/2004, with respect to annular aspiration lumen have been fully considered and are persuasive. The rejections of claims 12-17, 24-26 have been withdrawn. The prior art not only fails to disclose an annular lumen used for aspiration it teaches away from using the annular lumen for aspiration (see Underwood et al. col. 21, lines 42-65 and figure 10).

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Claims 1-11, 18, 19, 21 and 22 are still rejected as they do not recite the aspiration lumen being an annular lumen.

It should be noted that claim 23 is still interpreted as a duplicate of claim 20.

Beginning on page 2 of 3, line 21, Applicant asserts that the combination of the prior art of record does not disclose or suggest "supplying thermal energy to the electrode so as to treat the tissue whereby the warmed irrigating solution inhibits undesirable heating below the surface of the tissue," as recited in claim 1. As is well known in the art saline is a dispersive medium in that it conducts electrical current with noticeable energy loss. This lost energy is simply the thermal energy of the fluid as it heats up. The saline inhibits undesirable heating below the surface of the tissue by absorbing the conducted electrical energy. Additionally, strictly speaking thermal energy is not supplied to the electrode. Electrical energy (in the form of RF current see claims 8 and 9) is supplied to the electrode and as a consequence of the conduction of electrical energy and inherent and natural resistive properties of the materials involved, thermal energy is created (or rather some of the electrical energy is transformed into thermal energy) due to the resistive properties of the materials involved. Applicant has not presented a disclosure that enables one of ordinary skill in the art to understand how the claimed method is performed when "thermal energy" is supplied to the electrode. The examiner has interpreted the "supplying of thermal energy" to mean the supplying of electrical energy with the inherent presence of thermal energy as a byproduct of the conduction of electrical energy through resistive materials.

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Finally, the examiner has previously considered, initialed and signed the IDSs submitted on February 25, 2002 and September 9, 2003 wherein two PTO-FOM 1449s (4 pages from February 25, 2002, and 12 pages from September 9, 2003) were completed. The examiner provides a copy of the previously reviewed, initialed, signed and dated 1449s.

This is a Non-Final rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R.

May 27, 2004

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER